F867
(Rev.)

§483.75(c) Program feedback, data systems and monitoring.

A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:

§483.75(c)(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.

§483.75(c)(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at §483.7*1* and including how such information will be used to develop and monitor performance indicators.

§483.75(c)(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.

§483.75(c)(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

§483.75(d) Program systematic analysis and systemic action.

§483.75(d)(1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

§483.75(d)(2) The facility will develop and implement policies addressing:

- **(i) How they will use a systematic approach to determine underlying causes of problems impacting larger systems;**
- **(ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems; and**
- **(iii)How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.**

§483.75(e) Program activities.

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§483.75(e)(1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.

§483.75(e)(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the facility.

§483.75(e)(3) As part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at §483.7*1*. Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.

§483.75(g) Quality assessment and assurance.

§483.75(g)(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:

- **(ii) Develop and implement appropriate plans of action to correct identified quality deficiencies;**
- **(iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.**

INTENT

These provisions are intended to ensure facilities obtain feedback, use data, and take action to conduct structured, systematic investigations and analysis of underlying causes or contributing factors of problems affecting facility-wide processes that impact quality of care, quality of life, and resident safety.

DEFINITIONS

"Adverse Event" is defined in §483.5 as an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.

"Corrective Action" *refers to* a written and implemented plan of action for correcting or improving performance in response to an identified quality deficiency. Use of the term corrective action in this guidance is not synonymous with a Plan of Correction (formal response to cited deficiencies). This is also separate from the written QAPI plan.

"Health equity" *refers to the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless*

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of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. From the CMS Framework for Health Equity, April 2022, https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.

"High-risk areas" *r*efers**:** Refers to care or service areas associated with significant risk to the health or safety of residents. Errors in these care areas have the potential to cause adverse events resulting in pain, suffering, and/or death. Examples include tracheostomy care; pressure injury prevention; administration of high-risk medications such as anticoagulants, insulin, and opioids.

"High-volume areas" *r*efers to care or service areas performed frequently or affecting a large population, thus increasing the scope of the problem, e.g., transcription of orders; medication administration; laboratory testing.

"Incidence" *refers to* a measure of the number of new cases of a characteristic that develop in a population in a specified time period. National Institute of Mental Health (NIMH) (https://www.nimh.nih.gov/health/statistics/what-is-prevalence.shtml, accessed 12/21/2020).

"Indicator" *refers to* measurement of performance related to a particular care area or service delivered. Used to evaluate the success of a particular activity in achieving goals or thresholds.

"Medical Error" *refers to* a deviation from the process of care, which may or may not cause harm to the resident.

"Near Miss" *refers to* a serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. It is also called a potential adverse event.

"Prevalence" *refers to* the proportion of a population who have a specific characteristic in a given time period. NIMH (https://www.nimh.nih.gov/health/statistics/what-is-prevalence.shtml, accessed 12/21/2020).

"Problem-prone areas" refers to care or service areas that have historically had repeated problems, e.g., call bell response times; staff turnover; lost laundry.

"Quality Assurance and Performance Improvement (QAPI)" *refers to* the coordinated application of two mutually reinforcing aspects of a quality management system: Quality Assurance (QA) and Performance Improvement (PI). QAPI takes a systematic, interdisciplinary, comprehensive, and data-driven approach to maintaining and improving safety and quality in nursing homes while involving residents and families, and all nursing home caregivers in practical and creative problem solving.

- **Quality Assurance (QA)** *refers to* the specification of standards for quality of

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care, service and outcomes, and systems throughout the facility for assuring that care is maintained at acceptable levels in relation to those standards. QA is on-going and both anticipatory and retrospective in its efforts to identify how the organization is performing, including where and why facility performance is at risk or has failed to meet standards.

- **Performance Improvement (PI):** PI (also called Quality Improvement - (QI) *refers to* is the continuous study and improvement of processes with the intent to improve services or outcomes, and prevent or decrease the likelihood of problems, by identifying opportunities for improvement, and testing new approaches to fix underlying causes of persistent/systemic problems or barriers to improvement. PI in nursing homes aims to improve facility processes involved in care delivery and enhanced resident quality of life. PI can make good quality even better.

"Quality Deficiency (or Opportunity for Improvement)" *refers to a* deviation in performance resulting in an actual or potential undesirable outcome, or an opportunity for improvement. A quality deficiency is anything the facility considers *needing* further investigation and correction or improvement. Examples include problems such as medical errors and accidents, as well as improvement opportunities such as responses to questionnaires showing decreased satisfaction. This term is not necessarily synonymous with a noncompliance deficiency cited by surveyors, but may include issues related to deficiencies cited on annual or complaint surveys.

"Systematic" *refers to* a step by step process that is structured, so that it can be replicated.

"Systemic" *refers to* embedded within, and affecting a system or process.

GUIDANCE

As required in §483.75(a) (F865), the facility must develop and implement systems that ensure the care and services it delivers meet acceptable standards of quality in accordance with recognized standards of practice. This is accomplished, in part, by identifying, collecting, analyzing and monitoring data which reflects the functions of each department and outcomes to residents.

Feedback

Feedback is one of many data sources which provide valuable information the facility must incorporate into an effective QAPI program. Each facility must establish and implement written policies and procedures for feedback.

Feedback must be obtained from direct care staff, other staff, residents and resident representatives, as well as other sources, and be used to identify problems that are high-risk, high-volume, and/or problem-prone, as well as opportunities for improvement. Feedback from residents is necessary to understand what quality concerns are important to them, their perspectives, values and priorities, as well as the impact of the facility's daily routines on their physical, mental, and psychosocial well-being. Staff can also provide valuable input into understanding care and service delivery processes. *Facilities*

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should consider feedback related to concerns about health equity. For example, does the facility address the needs of individuals with disabilities, limited English proficiency, with different cultural or ethnic preferences, or other health equity concerns? Additional information on addressing health equity can be found at the CMS Framework for Health Equity site, https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.

A facility should choose the best mechanism for feedback to support their QAPI program. Examples of mechanisms for obtaining resident and staff feedback may include, but are not limited to:

- Satisfaction surveys and questionnaires;
- Routine meetings, e.g., care plan meetings, resident council, safety team, town hall; and
- Suggestion or comment boxes

Effective feedback systems in a QAPI program also include methods for providing feedback to direct care staff, other staff, residents and representatives. This may involve including these individuals in problem solving, various meetings or providing updates and communicating facility system changes.

Data Collection Systems and Monitoring

In order to ensure care and services are carried out consistently, accurately, timely and according to recognized standards of quality, the facility must collect and monitor data reflecting its performance, including adverse events.

Facility policies and procedures must address how data will be identified, and the frequency and methodology for collecting and using data from all departments. The facility determines what data it will collect to represent its care areas considered to be associated with high-risk, high-volume, and/or problem-prone issues. *Facilities should also collect and monitor data related to the outcomes of sub-populations to address any health equity issues. For example, there could be higher risk or problem-prone issues related to certain sub-populations (e.g., race, sexual orientation, socioeconomic status, or preferred language) within the facility.*

Data collection can be done using several methods, such as audit tools (purchased or developed by the facility), direct observation, interview, or testing. Sources for data may include the Minimum Data Set (MDS) and Quality Measures, electronic and paper medical records, survey results, incident reports, complaints, suggestions and staffing data. CMS expects the data collection methodology to be consistent, reproducible and accurate to produce data that are valid and reliable and support all departments and the facility assessment (§483.71).

It is not necessary to collect all data at the same frequency. The facility may develop a schedule for routine data collection. For example, data related to high-risk or problem-prone issues will generally be collected more frequently (e.g. daily, weekly, or monthly)

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until performance is at a satisfactory level, then collected less frequently (e.g. quarterly or every six months).

Performance Indicators
The facility must have policies and procedures in place for developing, monitoring and evaluating performance indicators. The policies and procedures must also describe how and with what frequency the facility develops, monitors and evaluates its performance indicators.

A performance indicator is a measurement of from the data collected, which represents performance in a specific care or service area. Performance indicators enable the facility QAA Committee to establish performance thresholds and goals, identify deviations in performance and evaluate progress. An example of monitoring includes comparing results of facility performance over time, as well as to state or national benchmarks.

Systematic Analysis and Action
As part of its' QAPI program, each facility is responsible for having systems in place and implementing actions intended to improve performance. This includes implementation of corrective actions, measuring success, and tracking performance, to ensure improvements are achieved and sustained.

The facility must develop and implement policies and procedures which address:

- How it will use systematic approaches (such as root cause analysis, reverse tracker methodology, or health-care failure and effects analysis) to assist in determining underlying causes of problems impacting larger systems.
- How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems; and
- How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.

Establishing Priorities
The facility must establish priorities for performance improvement activities that focus on resident safety, health outcomes, autonomy, choice and quality of care, as well as high-risk, high-volume, and/or problem-prone areas. When determining priorities, the facility must also consider the incidence, prevalence and severity of problems or potential problems identified. *Consideration should also be given to factors that affect health equity and outcomes depending on the population of residents within the facility.*

If systemic concerns, especially repeat survey deficiencies, have not been identified or prioritized by the facility's QAA committee, this may be an indication that the committee is not performing its required functions effectively.

Medical Errors and Adverse Events
In addition to self-identified improvement activities, the facility must also track medical errors and adverse resident events. When medical errors or adverse resident events are identified, the facility must analyze the cause of the error/event, implement corrective

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actions to prevent future events, and conduct monitoring to ensure desired outcomes are achieved and sustained.

Nursing homes must develop and implement written policies and procedures that enable the facility to systematically identify and investigate for medical errors and adverse events, including how the facility will analyze and use data relating to errors/events to develop activities to prevent future occurrences. *Data analysis should include an evaluation of factors known to affect health equity, such as race, sexual orientation, socioeconomic status, or preferred language.*

In 2014, the Department of Health and Human Services, Office of Inspector General (OIG) released its report "Adverse Events in Skilled Nursing Facilities (SNFs): National Incidence Among Medicare Beneficiaries," which found that one in three Medicare beneficiaries were harmed by an adverse event or temporary harm event within their first 35 days while residing in a SNF. The OIG determined that nearly sixty percent of the events were potentially preventable. The OIG classified the events into three categories: medication, care, and infection related adverse events.

CMS collaborated with the Agency for Healthcare Research and Quality (AHRQ) to develop a listing of common potentially preventable events that occur in nursing homes – this list is not all-inclusive of potentially preventable events. This list is subject to change as technology and research redefine what is preventable.

Potentially Preventable Events Related to:		
Medication	**Care**	**Infection**
Change in mental status/delirium related to use of opiates and psychotropic medication	Falls, abrasions/skin tears, or other trauma related to care	Respiratory infections: • Pneumonia • Influenza
Potentially Preventable Events Related to:		
Hypoglycemia related to use of antidiabetic medication	Electrolyte imbalance (including dehydration and acute kidney injury/insufficiency) associated with inadequate fluid maintenance	Skin and wound infections: • Surgical Site Infections (SSIs) • Soft tissue and non-surgical wound infections
Ketoacidosis related to use of antidiabetic medication	Thromboembolic events related to inadequate resident monitoring and provision of care	Urinary tract infections (UTIs) • Catheter Associated UTIs (CAUTIs) • UTIs (non-catheter associated)

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Bleeding related to use of antithrombotic medication	Respiratory distress related to inadequate monitoring and provision of tracheostomy/ventilator care	Infectious diarrhea • Clostridium difficile • Norovirus
Thromboembolism related to use of antithrombotic medication	Exacerbations of preexisting conditions related to inadequate or omitted care	
Prolonged constipation/ileus/ impaction related to use of opiates	Feeding tube complications (aspiration, leakage, displacement) related to inadequate monitoring and provision of care	
Electrolyte imbalance (including dehydration and acute kidney injury) related to use of diuretic medication	In-house acquired/worsened stage pressure injuries, and unstageable/suspected deep tissue injuries	
Drug toxicities including: acetaminophen, digoxin; levothyroxine; ACE inhibitors; phenytoin; lithium; valproic acid; antibiotics	Elopement	

Potentially Preventable Events Related to:		
Altered cardiac output related to use of cardiac/blood pressure medication	Instances of abuse, neglect, and misappropriation of resident property and exploitation (see §483.5)	

According to the OIG report, preventable adverse events were generally caused by:

- Appropriate treatment provided in a substandard way (56%)
- Resident's progress not adequately monitored (37%)
- Necessary treatment not provided (25%)
- Inadequate resident assessment and care planning (22%)

As part of the facility's performance improvement activities to reduce medical errors and adverse events, feedback and learning must be provided throughout the facility (483.75(e)(2)). Educating staff, residents, resident representatives and family members on medical errors and adverse events, such as what to look for and preventive measures, are important factors in reducing and preventing medical errors and adverse resident events.

For additional information regarding QAPI training requirements see §483.95(d), (F944).

Identifying Quality Deficiencies and Corrective Actions

The QAA committee's responsibility to identify quality deficiencies requires facilities to have a system for monitoring departmental performance data routinely in order to identify deviations in performance and adverse events. Adverse events, such as the elopement of a cognitively-impaired resident, should be considered a high risk problem for which corrective action is required.

Once a quality deficiency is identified, the QAA committee has a responsibility to oversee development of an appropriate corrective action. An appropriate corrective action is one that addresses the underlying cause of the issue comprehensively, at the systems level.

There are many different methodologies available to facilities for developing corrective action. CMS has not prescribed a particular method that must be used. Corrective action generally involves a written plan that includes:

- A definition of the problem – which includes determining contributing causes of the problem;
- Measurable goals;
- Step-by-step interventions to correct the problem and achieve established goals; and
- A description of how the QAA committee will monitor to ensure changes yield the expected results.

Corrective actions may take the form of one or more tests of change, or Plan-Do-Study-Act (PDSA) cycles until the desired performance goals have been met, or the facility may conduct a Performance Improvement Project.

Performance Improvement Projects (PIPs)

The facility must conduct distinct performance improvement projects, based on the scope and complexity of facility services and available resources, identified as a result of the

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facility assessment required at §483.71. While the number and frequency of improvement projects may vary, each facility must conduct at least one improvement project annually that focuses on high-risk or problem-prone areas, identified by the facility through data collection and analysis.

PIPs are a process that generally involves a team making a concentrated effort over time to improve a systemic problem or improve quality in absence of a problem. PIPs often require a systematic investigation, such as a Root Cause Analysis (RCA) to identify underlying causes or factors which have contributed to or caused the problem and the development of a corrective action plan. Interventions are designed to address the underlying causes, and once implemented, the team closely monitors results to determine if changes are yielding the expected improvement or if the interventions should be revised.

The facility's action plans to address quality deficiencies and improve performance may be implemented in a variety of ways, including staff training and deployment of changes to procedures; monitoring and feedback mechanisms; and processes to revise plans that are not achieving or sustaining desired outcomes. The committee may delegate the implementation of action plans to various facility staff and/or outside consultants.

Quality assessment and assurance
Functioning under the facility's governing body, the QAA committee is responsible for:

- Developing and implementing appropriate plans of action to correct identified deficiencies;
- Regularly reviewing and analyzing data, including data collected under the QAPI program and data resulting from drug regimen reviews; and
- Acting on available data to make improvements.

For concerns related to governance and leadership and the governing body and/or executive leadership, see §483.75(f), (F865).

INVESTIGATIVE PROCEDURE
Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) and Quality Assessment and Assurance (QAA) Review, along with the above interpretive *guidance* when determining if the facility meets the requirements for, or investigating concerns related to QAPI/QAA.

Surveyors should refer to the following when investigating concerns and citing non-compliance related to QAPI:

- F865: For concerns related to whether a facility has implemented and maintains a comprehensive QAPI program and plan, disclosure of records and governance and leadership.
- F867: For concerns related to how the facility obtains feedback, collects data, monitors adverse events, identifies areas for improvement, prioritizes improvement activities, implements corrective and preventive actions, and conducts performance improvement projects.
- F868: For concerns related to the composition of the QAA committee, frequency of meetings and reporting to the governing body.

KEY ELEMENTS OF NON-COMPLIANCE

To cite deficient practice at F867, the surveyor's investigation *will* must generally show that the facility failed to do any one of the following:

- Include in its policies and procedures how it obtains and uses feedback from residents, resident representatives, and staff to identify high-risk, high-volume, or problem prone issues as well as opportunities for improvement; or
- Develop and implement policies and procedures which include how it ensures data is collected, used and monitored for all departments; or
- Develop and implement policies and procedures for how the facility develops, monitors and evaluates performance indicators and the frequency for these activities; or
- Develop policies and procedures for how it will identify, report, and track, adverse events, and high risk, high volume, and/or problem-prone concerns; or
- Establish priorities for its improvement activities, that focus on high-risk, high-volume or problem-prone areas, as well as resident safety, choice, autonomy, and quality of care; or
- Ensure the QAA Committee developed and implemented action plans to correct identified quality deficiencies; or
- Measure the success of actions implemented and track performance to ensure improvements are realized and sustained; or
- Track medical errors and adverse events, analyze their causes, and implement preventive actions and mechanisms; or
- Conduct at least one PIP annually that focuses on high-risk or problem prone areas, identified by the facility, through data collection and analysis; or
- Ensure the QAA Committee regularly reviews and analyzes data collected under the QAPI program and resulting from drug regimen reviews, and act on the data to make improvements.

DEFICIENCY CATEGORIZATION

Examples of Level 4, immediate jeopardy to resident health or safety include, but are not limited to:

- Evidence showing one or more residents received third degree burns from hot water temperatures in the month prior to the survey. QAPI review showed the facility failed to use (e.g. review or analyze) the data they collected for routine monitoring of hot water temperatures throughout the facility. The failure of the facility to use the data it collected, resulted in lack of action to correct the systemic, high-risk issue, which created a situation where some residents were likely to experience serious injury, harm, impairment, or death.
- Evidence showing the facility failed to monitor their system for communicating each residents' code status. This resulted in staff having inaccurate and inconsistent information to use in emergency situations. QAPI review showed the QAA committee was not aware of this high-risk, systemic issue, and was not monitoring facility practices related to accurate and consistent communication of residents' advance directives and code status.

***An e*xample~~s~~ of Level 3, actual harm that is not immediate jeopardy include*s*, but *is* not limited to:**

- Evidence showing the facility had repeat deficiencies for the past two surveys related to their failure to ensure residents' post discharge needs were care planned

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and met upon discharge. During the current survey it was determined that a resident was discharged with no education about how to manage his new onset diabetes, resulting in his rehospitalization. The QAPI review showed the QAA committee was not aware of the issue and was not monitoring practices around discharge.

An example of Level 2, no actual harm with potential for more than minimal harm, that is not immediate jeopardy includes, but is not limited to:

- Facility failed to correct and monitor a quality deficiency identified on the previous survey, involving inaccurate weight measurement. This issue has the potential to cause more than minimal harm.

An example of Level 1, no actual harm with potential for minimal harm includes, but is not limited to:

- Facility failed to ensure that monitoring occurred as planned for an identified quality deficiency. On interview it was determined that the facility's corrective action involved monitoring monthly for three months to ensure the issue was corrected, however, documentation showed that for the second month, there was no evidence that monitoring had occurred.